NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

2015 Annual Convention

Date:	Saturday, October 10, 2015
Time:	3:00 pm – 4:30 pm
Location:	Gaylord National Harbor Resort and Convention Center, National Harbor 10
Title:	NCPA Advocacy Center, Regulatory and State Government Affairs Update ACPE # 207-000-15-112-L03-P · 0.15 CEUs ACPE # 207-000-15-112-L03-T
Activity Type:	Application-based
Speakers:	Steve Pfister, Senior Vice President, Government Affairs, NCPA Ronna Hauser, Vice President, Pharmacy Affairs, NCPA Susan Pilch, Vice President, Policy & Regulatory Affairs, NCPA Matt DiLoreto, Senior Director, State Government Affairs, NCPA

Pharmacist and Pharmacy Technician Learning Objectives:
Upon completion of this activity, participants will be able to:
1. Identify current federal and state legislative and regulatory activities that affect community pharmacy.
2. Discuss how efforts to regulate PBMs will increase transparency and the ability to negotiate with PBMs.
3. Discuss NCPA's model state pharmacy legislation.

Disclosures:
Steve Pfister declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Ronna Hauser declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Susan Pilch declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Matt DiLoreto declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

NCPA's education staff declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

NCPA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is accredited by NCPA for 0.15 CEUs (1.5 contact hours) of continuing education credit.

Community Pharmacy: Leveraging Our Strengths to Win

Steve Pfister, Senior Vice President of Government Affairs
Ronna Hauser, Vice President of Pharmacy Affairs
Susan Pilch, Vice President of Policy & Regulatory Affairs
Matt DiLoreto, Senior Director State Government Affairs

Disclosures

Steve Pfister declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Ronna Hauser declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

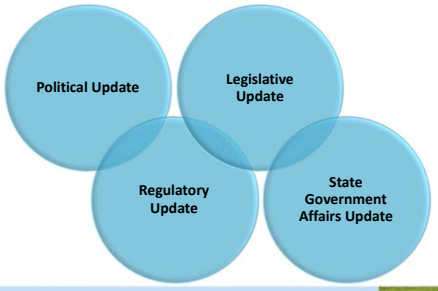
Susan Pilch declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Matt DiLoreto declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Learning Objectives

1. Identify current federal and state legislative and regulatory activities that affect community pharmacy.
2. Discuss how efforts to regulate PBMs will increase transparency and the ability to negotiate with PBMs.
3. Discuss NCPA's model state pharmacy legislation.

Overview



NCPA Government Affairs Team in Washington

Legislative Affairs Team

- Seasoned Capitol Hill veterans working to advance independent community pharmacy interests in the U.S. House and Senate

Regulatory and Policy Team

- In-house attorney and pharmacists analyzing legislation, drafting language and comments, and helping to favorably shape major federal legislation and regulation

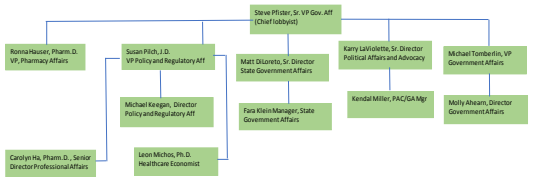
State Affairs Team

- Working closely with NCPA membership and state associations to provide support in individual states and ensuring that independent pharmacy victories will be the road map to future federal legislation

Political Development Team

- Working continuing to support our Capitol Hill Champions and strengthen the voice of independent pharmacy

NCPA Government Affairs Team



Political Update

New House Leadership

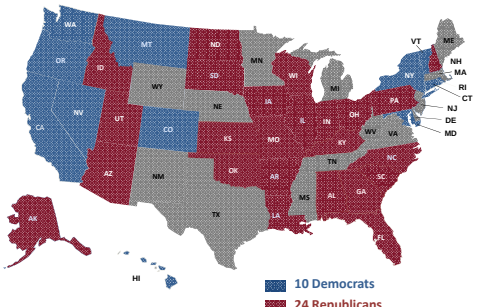
September 2015

- Speaker – John Boehner (R-OH-8)
- Majority Leader – Kevin McCarthy (R-CA-23)
- Majority Whip – Steve Scalise (R-LA-1)
- Conference Chair – Cathy McMorris Rodgers (R-WA-5)

October 2015

- Speaker – Kevin McCarthy (R-CA-23), Jason Chaffetz (R-UT-3), other?
- Majority Leader – Steve Scalise (R-LA-1), Tom Price (R-GA-6)?
- Majority Whip – Patrick McHenry (R-NC-10), Pete Sessions (R-TX-32)?
- Conference Chair –Cathy McMorris Rodgers (R-WA-5)

2016 Senate Elections



Senators up for Re-Election in 2016

Democrats

CA	Barbara Boxer – OPEN
CO	Michael Bennet
CT	Richard Blumenthal
HI	Brian Schatz
MD	Barbara Mikulski - OPEN
NV	Harry Reid - OPEN
NY	Chuck Schumer
OR	Ron Wyden
VT	Pat Leahy

All 10 Democratic seats in states Obama won twice

Republicans

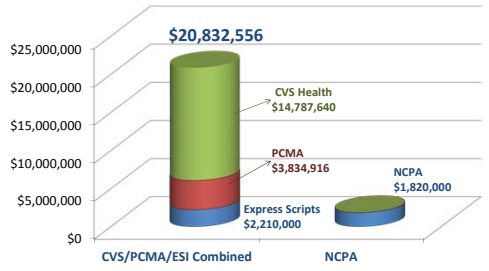
AL	Richard Shelby	ND	John Hoeven
AK	Lisa Murkowski	OH	Rob Portman
AZ	John McCain	OK	James Lankford
AR	John Boozman	PA	Pat Toomey
FL	Marco Rubio	SC	Tim Scott
GA	Johnny Isakson	SD	John Thune
ID	Mike Crapo	UT	Mike Lee
IL	Mark Kirk	WI	Ron Johnson
IN	Dan Coats – OPEN		
IA	Chuck Grassley		
KS	Jerry Moran		
KY	Rand Paul		
LA	David Vitter		
MO	Roy Blunt		
NH	Kelly Ayotte		
NC	Richard Burr		

7 Republican Senators running in states carried by Obama twice

Political Lay of the Land

- House Republicans have the largest working majority since the Hoover administration in 1931 with 247 seats. Is it "working"?
- Senate Republicans need 6 Democrats to pass any legislation (60 vote threshold)
- Obama administration: Confrontation or Cooperation?
- Senate R's need 13 Democrats to override Presidential veto
- 2016 Presidential race looming. Who are the front runners?
- Since WWII only once has a political party won the White House in 3 consecutive elections

2014 Lobbying Expenses



Source: Lobbying Disclosure Reports filled with the U.S. Senate and House of Representatives (1/1/14-12/31/14)

Legislative Update

Challenging Atmosphere for Community Pharmacy

Massive debts and yearly deficits in the federal government and state governments increases pressure on the public health programs

The entirety of our reimbursement and general business are now affected by middlemen PBMs

2015 NCPA Membership Priorities

- Passing state and federal MAC bills to address delays in generic prescription payment rate updates
- "Any Willing Pharmacy" having access to Medicare Part D Preferred Networks
- Regulatory advocacy on new definitions of how Medicaid calculates its payments to pharmacies (i.e. NADAC)
- Pharmacist Provider Status
- Small business tax reform

Key Legislative Priorities

- **Generic Drug Pricing Transparency and Timely Updates**
- **Fairness in Part D Preferred Pharmacy Networks**
- **Recognition as Provider in Medicare Part B**

The MAC transparency Act H.R. 244

- Introduced in the House by Reps. Doug Collins (R-GA) and Dave Loebsack (D-IA) on January 9, 2015 and has 28 co-sponsors
- The legislation would increase transparency of generic drug payment rates in Medicare Part D, the Federal Employees Health Benefits Program (FEHB) and TRICARE, by requiring PBM's to:
  - Provide pricing updates at least once every seven days
  - Disclose the sources used to update MAC prices
  - Notify pharmacies of any changes in individual drug prices in advance of reimbursement for claims
  - Establish an appeals process to resolve disputes when drug prices are less than the acquisition cost of a drug
  - Protect patient privacy and choice in Part D and FEHB by prohibiting a PBM from requiring that a beneficiary use a retail or mail order pharmacy in which the PBM has an ownership interest

Ensuring Seniors Access to Local Pharmacies Act H.R. 793/S.1190

- This bi-partisan "Any Willing Pharmacy" legislation would allow community pharmacies located in medically underserved areas (MUA's), medically underserved populations (MUP's) or health professional shortage areas (HPSA's) to participate in Medicare Part D preferred pharmacy networks so long as they are willing to accept the contract terms and conditions that other in-network providers operate under
- H.R. 793 was introduced in the House by Reps. Morgan Griffith (R-VA) and Peter Welch (D-VT) on February 5, 2015 and currently has 58 co-sponsors
- S. 1190 was introduced in the Senate by Sens. Shelly Moore Capito (R-WV), Tom Cotton (R-AR), Joe Manchin (D-WV) and Sherrod Brown (D-OH) on May 5, 2015 and has 10 co-sponsors

Pharmacy and Medically Underserved Areas Enhancement Act (Provider Status) H.R. 592/S.314

- This legislation would permit pharmacists in medically underserved communities to both provide and be reimbursed under Medicare Part B for services outlined in their state's existing scope of practice
- The legislation is consistent with precedent established by the Nurse Practitioners (NP's) and Physicians' Assistants (PA's) provider status efforts; pharmacist services would be reimbursed at 85% of the physician fee schedule
- H.R. 592 was introduced in the House by Reps. Brett Guthrie (R-KY), Todd Young (R-IN), G.K. Butterfield (D-NC) and Ron Kind (D-WI) and currently has 211 co-sponsors (218 House Majority)
- S. 314 was introduced by Sens. Chuck Grassley (R-IA), Sherrod Brown (D-OH), Mark Kirk (R-IL) and Bob Casey (D-PA) on January 29, 2015 and currently has 31 co-sponsors

Regulatory Issues

TRICARE

<u>TBD TRICARE preferred pharmacy pilot included in NDAA 2016</u>

House bill:

- Amendment offered by Rep. Austin Scott (R-GA) adopted prior to passage
- Provides small business community pharmacy the opportunity to participate at a rate no less than small business pharmacies currently participate in serving TRICARE patients.
- The pilot will enable pharmacies willing to participate in the pilot, which will be conducted in one region, the ability to purchase drugs for their TRICARE patients at the greatly reduced Federal Supply Schedule rate.
- NCPA fought for its members to be included in the pilot
- The final NDAA (House/Senate Conference) did not include the pilot and is likely to be vetoed by the President

TRICARE

TRICARE Brand Rx Changes In Effect as of October 1st

- All TRICARE beneficiaries, except active duty service members, must get select brand name maintenance drugs through either TRICARE mail order or from a military pharmacy
- TRICARE patients can continue to receive all generic drugs as well as drugs for shorter-term needs at their community pharmacy with no co-pay changes.
- Extension of the current TRICARE for Life pilot program that started in March 2014.
- Patients may be granted a waiver in limited scenarios such as an emergency, personal needs or special circumstances such as residing in a nursing home. Have patients or their caregivers call Express Scripts at 1-877-363-1303 to request a waiver.
- NCPA has prepared a one-page letter for TRICARE patients.
- A list of the select brand name maintenance drugs impacted can be found here: http://www.health.mil/selectdruglist.
- NCPA in contact with TRICARE leadership about extremely misleading letter, asking for clarification.

DQSA Where are We Now

Outstanding 503A issues:

1. Withdrawn/Removed List: FDA intends to update this list periodically, and expects compounders to comply with the list as it currently exists and with any final updates.
2. Bulk Drug Substances List: Until a bulk drug substances list is published in the Federal Register as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs.
3. "Demonstrable Difficulties" for Compounding: This provision is not enforceable until FDA promulgates an implementing regulation.
4. Memorandum of Understanding Between FDA and the States: FDA does not intend to enforce the 5% limit on interstate distribution until after FDA has finalized an MOU and made it available to the states for their consideration and signature.

DQSA Where are We Now

- Draft Repackaging Guidance
  - LTC Pharmacy Concerns
- FDA Listening Sessions
- FDA Pharmacy Compounding Advisory Committee
  - 14 Total Members 12 Voting 2 Non-voting
  - Temporary Members may be voting members

FDA PCAC

FDA Pharmacy Compounding Advisory Committee

1st meeting February 23-24, 2015

- withdrawn/removed list, 503A bulk substances list (64 total to be considered)

2nd meeting June 17-18, 2015

- expanded access to investigational drugs, withdrawn/removed list, 503A bulk substances list, proposed criteria for demonstrably difficult list

3rd meeting Late October 2015

DQSA Stakeholders

Broad Group of Prescribers, Pharmacists and Patients

DQSA Stakeholder Coalition Activities

- Office Use/Potential House Legislation
- Repackaging
- Appropriations
- Dietary Supplements
- Listening Session Response
- GAO report
- Senator Vitter bill (S. 1406)
- Demonstrably Difficult List
- Vet Compounding
- TRICARE

Coming Soon…

Updates to USP <797>

- Sterile compounding

New USP <800>

- Hazardous drug compounding
  - Sterile & non-sterile

Compounding Last But Not Least

Veterinary Medicine: FDA GFI #230

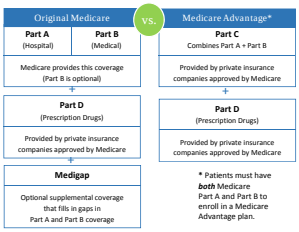
- HR 3204 only applies to human medicine
- GFI #230 seeks to apply several components to veterinary compounding
- Adds significant documentation burden to both veterinarians and pharmacists

Medicare Part D 2016 Landscape

2016 Low-Income Subsidy (LIS) Cost-Sharing Levels

Full Benefit Dual Eligible	Deductible	Copayments
Up to or at 100% Federal Poverty Level (FPL)	$0	$1.20 Generic/Preferred Multi-Source Drug $3.60 Other
Over 100% FPL	$0	$2.95 Generic/Preferred Multi-Source Drug $7.40 Other
Institutionalized Beneficiary	$0	$0
LIS Recipient (Full Subsidy)	Deductible	Copayments
Income at or below 135% FPL and limited resources[a]	$0	$2.95 Generic/Preferred Multi-Source Drug $7.40 Other
LIS Recipient (Partial Subsidy)	Deductible	Copayments
Income below 150% FPL and limited resources[a]	$74.00	Prior to Catastrophic Coverage Stage: • 15% Coinsurance During Catastrophic Coverage Stage: • $2.95 Generic/Preferred Multi-Source Drug • $7.40 Other

Medicare Part D 2016 Landscape



Medicare Part D 2016 Landscape

2016 Medicare Part D Prescription Drug Plans
Top 10 Plans*

Plan Name	Parent Company	Preferred Cost-Sharing Network	Preferred Cost-Sharing Network Includes Independents
AARP MedicareRx Preferred	UnitedHealth Group	Yes	No
SilverScript Choice	CVS Health	No	-
Humana Preferred Rx Plan	Humana	Yes	No
Humana Walmart Rx Plan	Humana	Yes	No
AARP MedicareRx Saver Plus	UnitedHealth Group	Yes	No
Humana Enhanced	Humana	Yes	No
Cigna-HealthSpring Rx Secure	Cigna	Yes	Yes
WellCare Classic	WellCare	No	-
Aetna Medicare Rx Saver	Aetna	Yes	Yes
First Health Part D Value Plus	Aetna	Yes	Yes

* Based on September 2015 enrollment

Medicare Part D 2016

- Part D AWP Changes
- Convenient Access to Preferred Cost Sharing Pharmacies (PCSPs)
- MTM CMR Completion Rates now an Official Star Rating
- Prescriber Identification and Enrollment
- FWA Training
- CMS Innovation Center Part D MTM Pilot
- MAC Updates
- DIR fees

Pharmacy "DIR" Fees

- "Direct and Indirect Remuneration" (DIR)- a term coined by CMS related to drug manufacturer rebates that would affect gross rx drug costs of Part D plans "that were not captured at point of sale"
- Pharmacy "DIR" fees now used as a "catch-all" term to encompass fees that are assessed on pharmacy after claim adjudication or after point of sale.
- Started out in Part D program—starting to see use in commercial plans

Types of Pharmacy DIR Fees

- "Pay to Play" DIR Fees: pharmacies assessed a fee to participate in a "preferred network." Assessed on flat per-claim basis or as flat percentage assessed at regular intervals
- Payment Reconciliation DIR Fees: the result of a reconciliation between target reimbursement rate in participating pharmacy agreement to an aggregated effective rate
- Performance Metric DIR Fees: pharmacies are evaluated under various metrics incl.; refill rates; preferred product rate, audit performance; in comparison to others in network

Top DIR Questions

- **Why are DIR fees starting to become more prevalent?**
  - Obscure true reimbursement amounts to pharmacy and to skirt state MAC transparency law
- **As Pharmacy Owner, What Can I Do?**
  - Due diligence in reviewing all contract terms and information from your contracting entity
- **Any Relief in Sight?**
  - CMS proposed guidance would require pharmacy price concessions (DIR fees) to be estimated or approximated at point of sale

2016 Part D MAC Enforcement

- January 1, 2016 Part D Plans/PBMs must: (1) provide network pharmacies access to MAC prices in advance of use for reimbursement; (2) Update MAC prices every 7 days; (3) Ensure MAC prices reflect "market price"
- NCPA provided recommendations to CMS re: suggested guidance: (1) CMS central MAC portal; (2) Use Wisconsin Medicaid MAC portal as "template" for PBMs; (3) Define "MAC" and "generic effective rate"—universal definition for contracts; (4) Require historical record of past MAC prices to allow comparison to PlanFinder and reimbursement validation

2016 Preferred Cost Sharing Disclaimer Language

- Plan sponsors must include specific disclaimer language in any marketing materials for 2016 plans that provide inadequate access to discounted co-pays at "preferred" pharmacies
- "X pharmacy network offers limited access to pharmacies with preferred cost sharing in [specific geographic type/state]. *The lower costs advertised in our plan materials for these pharmacies may not be available at the pharmacy you use*……"[NCPA statement incorporated]

Medicaid: AMP FULs/NADAC/AAC

- 2012-CMS Proposed Rule requiring states to pay Medicaid pharmacies based on "actual acquisition cost" plus a "professional dispensing fee"
- States may use AMP-based federal upper limits (FULs) OR survey pharmacies to determine actual acquisition cost OR use the National Average Drug Acquisition Cost (NADAC)-CMS pricing benchmark based on average invoice costs

Medicaid Reimbursement Continued

- Continued controversy over use of AMP-based FUL for pharmacy reimbursement: volatility in reported prices; for generics only; no less than 175% of AMP
- State Average Acquisition Cost (AAC); brand and generic drugs; 6 states currently adopted this approach w/dispensing fees ranging from $9.31-$15.11
- NADAC based on voluntary national surveys; brand and generic drugs; NADAC brand reimbursement equivalent to AWP minus 18.33% or WAC minus 2%; NADAC generic reimbursement range from AWP minus 75% and AWP minus 85%
- Three states have adopted NADAC w/dispensing fees ranging from $10 to $11.20

Implications of Medicaid Reimbursement

- Overall, NADAC more stable benchmark than AMP-based FULs
- Optimal to use NADAC for generics; WAC for brands
- Possibility of CMS adopting NADAC pricing for Part D
- Commercial plans starting to use NADAC?
- Reimbursement for specialty drugs?

Supply Chain Security

- November 1, 2015: Dispensers required to receive transaction data and pass transaction data if they further distribute
- Transaction information; transaction history; and transaction statement:
- Information must be captured and stored for 6 years; Able to be retrieved if requested by federal or state regulator
- Law allows "third parties" to capture and maintain data for the dispenser [Many wholesalers providing this service]

340B "Mega Guidance"

- On August 28, the Health Resources and Services Administration (HRSA) published its long-awaited "mega guidance" in the Federal Register
- The proposed guidance does not include any limitation on the number of contract pharmacies permitted to dispense 340B drugs
- A covered entity can contract with one or more licensed pharmacies to dispense 340B drugs to eligible patients
- While the proposed guidance would not materially limit or alter the 340B contract pharmacy model, it will likely reduce the number of eligible patients and narrow drug discounts.

340B "Mega Guidance"

- The proposed guidance would provide a more restrictive definition of 'covered patient,' increasing the number of conditions for patients to be eligible for discounted drugs from 3 to 6
- The guidance includes an updated record retention policy for covered entities – including 340B contract pharmacies – for a period of 5 years
- Covered entities would have to provide more direct oversight of a contract pharmacy, including an annual audit and quarterly review of the contract pharmacy program
- Regulatory guidance is different than an official regulation. It does not have the full force of law, but provides information concerning how the agency intends to administer the program
- HRSA established a 60-day public comment period (October 27)

State Government Affairs Update

Most Active State Legislative Issues in 2015

- MAC Transparency Legislation
  - 10 states (including Arkansas MAC strengthened)
- PBM Regulation and Enforcement
  - Incorporated into MAC (i.e. OK, GA, AR, OH, etc.)
- Medication Synchronization
  - 6 states
- Biosimilar Substitution
  - 10 states
- Any Willing Pharmacy / Provider

Overall State Legislative Successes

- **Generic Drug Pricing Transparency Legislation**
  - 24 States *(New York pending Governors signature)*
- **PBM Fair Audit**
  - 33 States
- **Anti-Mandatory Mail Order**
  - 8 States
- **Medication Synchronization**
  - 11 States

Most Notable Wins of 2015

- **Georgia** *(HB470)*
  - MAC Transparency & Strengthening of Fair Audit Law
  - Signed into law: May 2015
- **Arkansas** *(3 wins)*
  - Strengthening of MAC Transparency Law (SB688)
  - PBM Enforcement as TPA (SB487)
  - Patient Consent (SB542)
  - Signed into law: April 2015
- **Washington** *(SB5557)*
  - Pharmacist Recognition
  - Signed into law: May 2015
- **Ohio**
  - MAC transparency signed as part of state budget
  - Includes plan sponsor disclosure and notable enforcement.
  - Signed into law: June 30, 2015
  - Insurance Department interest and recognition of enforcement powers
- **Wisconsin**
  - MAC transparency signed as part of state budget
  - Signed into law: July 12, 2015

Evolving MAC Transparency Legislation

- **Original priorities:**
  - What information - "Sources utilized" - to determine MACs
  - Standardized disclosure of MACs to pharmacy (i.e. 7 days)
  - Standardization for what constitutes a "MAC'd" drug
  - Clearly defined appeals process for both pharmacy and PBMs
- **New priorities in addition to the above standards:**
  - PSAO or contracting agent relationship
  - Updated MACs must be "**utilized for reimbursement"**
  - NDCs must be **available** to **retail** pharmacies in the state
  - Enforcement mechanism(s)
- **On the Horizon:**
  - Addressing PBMs ability to circumvent intent of "MAC"
  - Updating NCPA Model Legislation

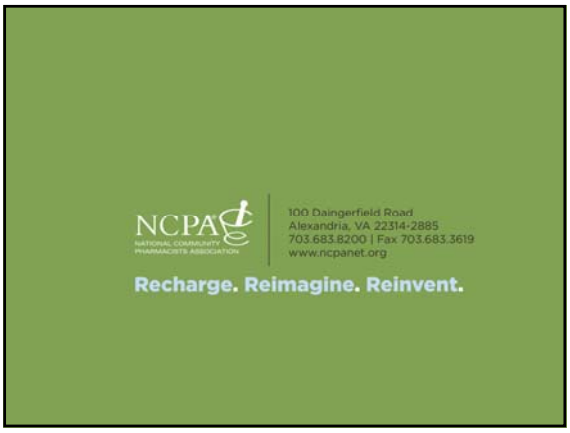
PBM Retaliation

- **Iowa MAC Transparency Lawsuit**
  - ERISA challenge victory
  - September 2015; Judge dismisses all of PCMA's challenges
- **Arkansas and Ohio Express Scripts Contract Amendment**
  - Distributed in response to MAC laws
- **Arkansas PCMA Lawsuit**
  - August 2015: PCMA files lawsuit challenging SB688/Act 900
    (I) is expressly preempted by ERISA;
    (II) is expressly preempted by Medicare Part D;
    (III) violates the Dormant Commerce Clause;
    (IV) violates the Federal Contracts Clause;
    (V) violates the Arkansas Contracts Clause;
    (VI) violates the Federal Due Process Clause; and
    (VII) violates the Arkansas Due Process Clause
  - September 22nd : AR filed a motion dismiss entire lawsuit
  - September 22nd : AR filed response for preliminary injunction

2016 Expectations

- **Legislative:**
  - New Generic Drug Pricing Transparency language
  - PBM Enforcement and Oversight Priority
  - Pharmacy Payment Equality
  - Any Willing Pharmacy
  - Implementation
- **Regulatory:**
  - AMP/FUL Implementation
  - AAC/NADAC

Questions?


NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
100 Daingerfield Road
Alexandria, VA 22314-2885
703.683.8200 | Fax 703.683.3619
www.ncpanet.org
Recharge. Reimagine. Reinvent.